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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/510,562	02/22/2000	Gerard Housey	395/35	3061

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EXAMINER

GUZO, DAVID

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 08/08/2003

37

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/510,562

Applicant(s)

HOUSEY, GERARD

Examiner

David Guzo

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 33,34,36,37,43-50,59-65,71-78 and 87-89 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33-34, 36-37, 43-50, 59-65, 71-78 and 87-89 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 34.
- 4) ☒ Interview Summary (PTO-413) Paper No(s) 36.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **Detailed Action**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/19/03 has been entered.

Applicants' amendments filed 5/19/03 are sufficient to overcome the outstanding rejections under 35 USC 102(b), 112, 1<sup>st</sup> paragraph and 112, 2<sup>nd</sup> paragraph. All outstanding rejections are therefore withdrawn.

The following new rejections are necessitated by applicants' amendment.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 33-34, 36-37, 43-44, 46, 47, 49-50, 63-65, 71-72, 74-75, 77-78, 88-89 are rejected under 35 U.S.C. 102(b) as being anticipated by Riedel et al.

Priority for the claimed invention is granted back to the filing date of the 07/392,073 application, filed 08/10/89.

Applicants claim methods for determining whether a chemical agent is a direct inhibitor or activator of a POI (enzyme) in a cell where expression of the POI results in a phenotypic characteristic in the cell, said method comprising providing a test mammalian cell line which produces said POI and exhibits a phenotypic response (which can be a graded cellular response) to the POI and wherein the level of the enzyme in the cell is maintained such that the cell is capable of exhibiting the phenotypic response following removal of the test chemical, providing a second mammalian cell line which is alike to the first cell line but which produces the POI at lower levels or not at all, incubating the test chemical with the first and second cell lines, comparing the phenotypic responses of the first and second cell lines to the test chemical and determining through use of a binding assay that the chemical agent directly binds to the POI.

Riedel et al. (cited by applicants, Science, Vol. 236, April 1987, pp. 197-200, see entire article, particularly the Abstract; Fig. 2-3; p. 198, last paragraph, p. 199, 3<sup>rd</sup> and 4<sup>th</sup> paragraphs, paragraph bridging the 2<sup>nd</sup> and 3<sup>rd</sup> columns) recites a method for determining whether an agent (epidermal growth factor, EGF) can activate or inhibit an enzyme (chimeric human epidermal growth factor (EGF) – avian *erbB* oncogene product, HER-*erbB*) expressed in a test mammalian cell. Expression of the HER-*erbB* gene product (as a result of transformation of test cells with a vector encoding the HER-*erbB* gene product, wherein said HER-*erbB* gene is under control of a promoter) causes a phenotypic change (graded cellular response) in the cells (cells are transformed, ability to grow in soft agar in the absence of EGF) and the level of the

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enzyme is maintained in the cell such that the phenotypic response following removal of the EGF is maintained. The agent EGF is incubated with the test cells and a control cell which does not produce the enzyme, the phenotypic responses (changes in cellular transformation, foci formation) of the two cells are compared and a binding assay is used to determine that the chimeric enzyme directly binds EGF. EGF is also used to treat the test cell to determine whether it exhibits a change in a graded cellular response (transformation response of cells in culture). EGF can be an activator of the HER-*erbB* enzyme under some circumstances (p. 199, top right column) and can be an inhibitor (p. 199, 3rd paragraph, left column) under other circumstances. The responsive change in a phenotype includes phosphorylation of an intracellular protein substrate of the enzyme. Riedel et al. therefore teaches the claimed invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33-34, 36-37, 43-50, 59-65, 71-78 and 87-89 are rejected under 35

U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Appellants have amended independent claims 33, 43, 59, 63 and 71 to recite generation of mammalian cells which produce the protein (enzyme) of interest (POI) and exhibit a phenotypic response to the POI and "...wherein the level of the enzyme in the cell is maintained such that the cell is capable of exhibiting the phenotypic response following removal of a direct activator or inhibitor of the enzyme...". The specification provides no support for this newly added limitation. The specification provides no support for generically practicing a screening method whereby expression of the POI is maintained in cells during and after binding with the putative inhibitor or activator so that the phenotypic response is exhibited by the cell after removal of the test agent.

Appellants also have amended the independent claims to recite the limitation of "...determining through the use of a binding assay that the chemical agent binds to the enzyme.". The specification provides no support for this newly added limitation. While applicants use a known phorbol ester binding assay to confirm that cells over expressing the protein kinase C also exhibit an increase in phorbol ester binding sites (pp. 31-32 of the instant specification), applicants do not disclose use of a binding assay to determine if the test chemical agent directly binds to the POI in the context of the claimed assay method. This is a NEW MATTER rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 87-89 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Multiple dependent claims 87-89 are in improper form because a multiple dependent claim must depend from other claims in the alternative only. See MPEP § 608.01(n). Redrafting the claims to recite "The method of any one of Claims..." or deleting "and" after the last two recited claim numbers in line 1 and substituting "or" would be remedial.


No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Faxes may be submitted directly to the examiner at (703) 746-5061.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David Guzo  
July 31, 2003

  
DAVID GUZO  
PRIMARY EXAMINER